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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,420	11/28/2000	Steven K. Yoshinaga	A-579C	7508

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EXAMINER

OUSPENSKI, ILIA I

ART UNIT PAPER NUMBER

1644

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/728,420

Applicant(s)

YOSHINAGA ET AL.

Examiner

ILIA OUSPENSKI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 56-82, 84 and 85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 56, 58, 65-69, 71, 75-78 and 80 is/are allowed.
- 6) ☒ Claim(s) 57, 59-64, 70, 72-74, 79, 81, 82, 84 and 85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

1. Applicant's amendment/remarks, filed 05/20/2005, are acknowledged.

Claim 83 has been cancelled.

Claims 1 – 55 have been cancelled previously.

Claims 56 – 63, 67 – 69, 72 – 76, 81 – 82, and 84 – 85 have been amended.

*Claims 56 – 82 and 84 – 85 are pending.*

2. This Office Action will be in response to applicant's arguments, filed 05/20/2005.

The rejections of record can be found in the previous Office Action, mailed 10/01/2004.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

It is noted that new grounds of rejection are set forth herein.

3. Applicant's amendment and argument have obviated the objections and rejections of record, except as set forth in section 4 infra. The disclosure of two species of B7RP1 proteins, in conjunction with a disclosed correlation between structure and function of B7RP1 e.g. at pages 23 – 24 and in Examples 3, 4, 7, 7 – 9, 11 – 14, and 17 – 21 of the specification appears to provide sufficient enablement and written description of the claimed invention.

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It is noted that for examination purposes, the recitation of "fully complementary" in claims 56(f) and 57(f) is interpreted as meaning complementarity over the full length of the respective sequences.

4. Claims 57, 59 – 64, 70, 72 – 73, 79, 81 – 82, and 84 – 85 stand rejected under **U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant has acknowledged the invitation by the Examiner to amend the Application to include the amino acid sequence of Gen Bank accession No. AB014553, but requested that consideration of such amendment be deferred until such time as all other outstanding rejection against the claims have been withdrawn.

Therefore, the rejection of record is maintained for the reasons of record. The rejection of record is reiterated herein for Applicant's convenience.

It is apparent that the amino acid sequence disclosed in GenBank Accession No. AB014553 is required for making and using the claimed invention. However, Applicant has not provided the sequence.

The amino acid sequence is considered essential subject matter to the instant application and the claimed invention.

Applicant has disclosed the sequence GenBank Accession number, however, this is not sufficient for a skilled artisan to envision the sequence referred to in the instant claims. Consequently, conception of the invention cannot be achieved until an appropriate written description of the structural and functional properties of the claimed invention has occurred. Adequate written description requires more than a mere statement that it is part of the invention. The sequence itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

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Applicant is invited to amend the instant specification to provide the essential subject of the amino acid sequence defining the claimed polypeptide, as set forth in GenBank Accession No.

AB014553. Further, Applicant is limited to the sequence defined by GenBank Accession No.

AB014553 at the time the invention was made.

Applicant is reminded to provide a Sequence Listing which complies with the requirements of 37 CFR 1.821 through 1.825 for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is further reminded to provide the appropriate Hawkins Declaration to accompany amending the instant specification to provide the amino acid sequence set forth in GenBank Accession No. AB014553.

The following is noted. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

**5. New grounds of rejection, necessitated by Applicant's amendment, are set forth herein.**

6. 35 U.S.C. § 101 reads as follows:

*"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".*

7. Claims 72 and 74 are rejected under **35 U.S.C. 101** because claimed invention is directed to non-statutory subject matter.

The claims, as presently recited, do not sufficiently distinguish over polypeptides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products.

The claims are drawn to a polypeptide comprising a fragment of an amino acid sequence as set forth in SEQ ID NO:12 (or at least 95% identical to SEQ ID NO:12), and has at least one activity selected from stimulating T-cell proliferation and/or activation, or binding to CRP1. As such, the claims read on a naturally occurring B7RP1 polypeptide.

In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). Amending the claims to recite an "isolated" or "recombinant" polypeptide variant, as e.g. in claim 342, would be remedial in overcoming this rejection. See MPEP 2105.

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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.*

9. Claim 74 is rejected under **35 U.S.C. 102(a)** as being anticipated by Ishikawa et al. (DNA Res., 1998, 5: 169 – 176; of record, see entire document) as evidenced by GenBank Accession No. AB014553 (released 02/06/1999, of record).

It is noted that Applicant's amendment to claim 74, which deleted the limitation "wherein the polypeptide does not have the amino acid sequence in GenBank Accession No. AB014553," renders the claim subject to the rejection of record, as set forth in the Office Action mailed 12/31/2002, section 20. The relevant part of the rejection of record, as it applies to the instant claim 74, as amended, is reiterated herein.

Ishikawa et al. teach gene number KIAA0653, and that the sequence information for the CDNA and the protein product of KIAA0653 is available under accession number AB014553 (see entire document, especially Table 1, first column). Ishikawa et al. also teach that the protein product of KIAA0653 was produced by in vitro translation (see comments in Section 2.1 on page 169 regarding original screening method) and that the 558 amino acid open reading frame encodes a protein of apparent molecular mass of 60 kDa (Table 1).

The protein product of KIAA0653 encompasses the entire amino acid sequence set forth in SEQ ID NO:12. Thus the protein product of KIAA0653 is a polypeptide comprising a fragment of at least about 50 amino acid residues of the instant SEQ ID NO:12. As the protein taught by Ishikawa et al. is the same as instantly claimed, it is inherent that the protein taught by Ishikawa et al. has the same functional properties as

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the instantly claimed protein, i.e. at least one activity selected from stimulating T-cell proliferation and/or activation, or binding to CRP1.

Therefore the reference teachings anticipate the instant claimed invention.

***10. Conclusion: claims 56, 58, 65 – 69, 71, 75 – 78, and 80 appear to be allowable.***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI

Patent Examiner

Art Unit 1644

August 10, 2005

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